

## REMARKS/ARGUMENTS

### Restriction/Election

The Office previously required election of a single invention between Group I (claims 1-11), Group II (claims 12-17), and Group III (claims 18-20). The applicant confirms previous telephonic election of *Group II without traverse, reading on claim 12-17. However, in view of the examiner's withdrawal of the restriction between Groups I and II, only claims 18-20 were withdrawn*, and claims 1-17 remain pending.

### 35 USC § 102(b)/103(a)

**Claims 1-5, 7-9, and 11** were rejected under 35 USC § 102(b) as being anticipated by Miljkovic (U.S. Pat. No. 5,962,049). The applicant respectfully disagrees, especially in view of the amendments made herein.

As amended herein, the claims expressly require that the kit includes "...an *instruction associated with the supplement indicating that ingestion of the supplement promotes bone health*..." Such element is not taught by Miljkovic. Consequently, claims 1-5, 7-9, and 11 are not anticipated by Miljkovic.

With respect to obviousness, the examiner stated that the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. With respect to the composition of matter, the applicant agrees. The boron complexes of the '049 reference are indeed to a very large extent, but not entirely, identical with those of the claims. However, it is pointed out that there is *no teaching, suggestion, or motivation in the '049 reference to use the claimed compositions with an instruction indicating that ingestion of the supplement promotes bone health*.

It is acknowledged that the '049 reference teaches that boron would provide benefits with respect to bone health (column 1, line 23). However, it is pointed out that *such teaching is made with respect to known boron-containing compositions* (column 1, lines 47-57), which suffer from various disadvantages. In this context, it should be particularly appreciated that the '049 patent teaches that the known compounds have an *almost immediate availability of boron* as the known forms of boron supplements either contain or are readily hydrolyzed in the gut to boric

acid, and as such will achieve *extremely high serum concentrations* as compared with normal boron blood values (column 1, lines 58 et seq.).

In contrast, the compounds of the presently pending claims expressly require that boron is tightly bound to the ligand, having an *association constant of at least 2,500* at equilibrium. In other words, in the equilibrium state of contemplated complexes, *only one out of 2,500 boron-ligand complexes is in a form where the boron atom is dissociated from its ligand*. Thus, using contemplated complexes for boron supplementation is not expected to provide immediate and significant concentrations of boron to a person ingesting such compounds. Clearly, a person of ordinary skill in the art *would not be motivated to employ such compounds in applications where relatively large quantities of boron are known to be required* (e.g., Nielsen teaches to use 3 mg/day, which equals a boron dose of about 0.3 mmol, while Naghii requires 10 mg/day, which equals a boron dose of about 1 mmol !). Therefore, claims 1-5, 7-9, and 11 should not be deemed obvious over Miljkovic.

### 35 USC § 103(a)

**Claims 1-17** were rejected under 35 USC § 103(a) as being obvious over Miljkovic (U.S. Pat. No. 5,962,049) in view of Naghii, Nielsen, and Volpe. The applicant respectfully disagrees, especially in view of the amendments made herein.

As amended herein, the claims expressly require that the kit includes "...an *instruction associated with the supplement indicating that ingestion of the supplement promotes bone health...*" and "...a *boron-ligand association constant of at least 2,500...*" Such elements are neither taught nor suggested by any combination of the cited references.

The examiner argues that the optimum daily intake of boron would be around 2-3 mg/day and that boron would be important in bone health. While the statements *per se* are not contested, it should be noted that the *prior art teaching of bone and dosage is with specific respect to known boron formulations*, all of which are characterized by almost immediate boron release (*supra*). Similarly, the '049 patent does teach boron complexes also claimed in the instant claims. However, such complexes in which boron is tightly bound with a  $K_A$  of at least 2,500 is clearly not contemplated to be employed in bone health aspects where very high dosages are required.

Again, reference is made to the observations above in which the applicant points out that *boron is strongly bound to the ligand*, which is in stark contrast to boron as bound in the compounds of the cited references. Therefore, a person of ordinary skill in the art would not be motivated to employ the compounds according to the present claims in compositions and methods for bone health.


With respect to methods of increase of steroids in a human according to claims 12-17, the same considerations apply in view of Naghii, as that reference expressly teaches administration of boron at a daily dose of 10 mg/day.

In view of the present amendments and arguments, the applicant believes that all claims are now in condition for allowance. Therefore, the applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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